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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,984	09/16/2005	Jean-Luc Jonniaux	VANM260.001APC	5006
20995 7590 09/21/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER JOIKE, MICHELE K	
			ART UNIT 1636	PAPER NUMBER
			NOTIFICATION DATE 09/21/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcarter@kmob.com  
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## Office Action Summary

Application No.

10/525,984

Applicant(s)

JONNIAUX ET AL.

Examiner

Michele K. Joike, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 18-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 18-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 2/25/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Specification***

The disclosure is objected to because of the following informalities: The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See paragraph 111.

Appropriate correction is required.

### ***Claim Objections***

Claim 9 is objected to because of the following informalities: Claim 9 is a Markush claim and should have the word "and" before *Myrothecium gramineum* in line 5. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10 and 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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It is apparent that *Myrothecium* strains MUCL39210, CBS449.71, IMI140595, IMI290405 and CBS328 are required to practice the invention. As such, the strains must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the strains. In the instant case, the process to generate the strains that is disclosed in the specification does not appear to be repeatable, nor does it appear the strains are readily available to the public.

- If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:
- a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
  - b) all restrictions upon availability to the public will be irrevocably removed upon the granting of the patent;
  - c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request for the enforceable life of the patent, whichever is longer;
  - d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and
  - e) the deposit will be replaced if it should ever become inviable.

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Failure to make one of the preceding indications in response to this Office Action will result in the rejection being maintained in either a second Non-Final or a Final rejection.

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that vectors PCNS43 and p3SR2 are required to practice the invention. As such, the vectors must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the vectors. In the instant case, the process to generate the vectors that is disclosed in the specification does not appear to be repeatable, nor does it appear the vectors are readily available to the public.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

- a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

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- b) all restrictions upon availability to the public will be irrevocably removed upon the granting of the patent;
- c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request for the enforceable life of the patent, whichever is longer;
- d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and
- e) the deposit will be replaced if it should ever become inviable.

Failure to make one of the preceding indications in response to this Office Action will result in the rejection being maintained in either a second Non-Final or a Final rejection.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 18-20 and 23-25 rejected under 35 U.S.C. 102(b) as being anticipated by US 6,180,366.

Applicants claim a *Myrothecium roridum* host cell comprising at least one recombinant DNA construct for an expression of heterologous genes, wherein said recombinant DNA construct is integrated into a chromosome of the host cell. The recombinant DNA construct comprises a nucleic acid sequence encoding a

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heterologous fungal protein, an *Aspergillus oryzae* TAKA-amylase promoter sequence, which is a regulatable, and a *niaD* selection marker sequence. Applicants also claim a method of genetically modifying *Myrothecium* cells to generate *Myrothecium* host cells comprising the steps of: growing *Myrothecium* cells, introducing into said *Myrothecium* cells at least one plasmid for a modulated expression for an expression of heterologous genes, and selecting genetically modified *Myrothecium* cells. Lastly, Applicants claim a method for producing a protein of interest, said method comprising the steps of: culturing *Myrothecium* host cells under conditions which permit expression of the protein; and recovering the protein from said *Myrothecium* cultured host cells. The protein is a fungal enzyme.

US 6,180,366 (specifically columns 3, 4, 7, 9 and 11-14) teaches a method of modifying a filamentous fungal cell, wherein the fungi can be the species *Myrothecium roridum*. The cell can contain a vector with an *Aspergillus oryzae* TAKA-amylase promoter sequence, which is a regulatable, a *niaD* selection marker sequence, and a gene of interest encoding a fungal enzyme, for example, a xylanase. Genetically modified *Myrothecium* cells with the *niaD* marker are selected. The vector can be integrated into the genome of the cell. The modified cell can be used to produce the fungal enzyme. The cells are cultured, and then the enzyme is isolated by purification.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-8 and 18-25 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,939,704.

Applicants claim a *Myrothecium* host cell comprising at least one recombinant DNA construct for an expression of heterologous genes. The recombinant DNA construct comprises a nucleic acid sequence encoding a heterologous fungal protein, a glucoamylase promoter of *Aspergillus niger*, which is a regulatable, and an *hph* selection marker sequence. Applicants also claim a method of genetically modifying *Myrothecium* cells to generate *Myrothecium* host cells comprising the steps of: growing *Myrothecium* cells, introducing into said *Myrothecium* cells at least one plasmid for a modulated expression for an expression of heterologous genes, and selecting genetically modified *Myrothecium* cells. The genetically modified cell has increased xylanase activity. The cell also has an altered metabolic pathway compared to a nontransformed *Myrothecium* cell. Lastly, Applicants claim a method for producing a protein of interest, said method comprising the steps of: culturing *Myrothecium* host cells under conditions which permit expression of the protein; and recovering the protein from said *Myrothecium* cultured host cells. The protein is a fungal enzyme. (xylanase)

US 6,939,704 (specifically columns 4-8 and 10-13) teaches genetic modification of fungi to enhance production of a protein of interest. The expression host can be *Myrothecium*. The host cell can be transformed with a vector containing a gene of interest, the regulatable glucoamylase promoter of *Aspergillus niger*, an *hph* marker, and a xylanase secretion signal. The gene of interest can encode the enzyme, xylanase from *T. reesei*. US 6,939,704 teaches a method for of introducing the genetic



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construct into the host cell in order to modify it, and then selecting for hygromycin resistance. The reference also teaches producing the xylanase and isolating it to check for activity. The modified cell also produces an increased amount of xylanase relative to an untransformed cell.

***Allowable Subject Matter***

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele K Joike, Ph.D.  
Examiner  
Art Unit 1636

  
DAVID GUZO  
PRIMARY EXAMINER